Preserving Independent Urology: LUGPA's First Decade

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> ince its initial charter as a trade organization representing the interests of urology practices of 10 physician members or more, LUGPA has expanded its mission to include smaller group practices that are equally committed to providing integrated, comprehensive services to patients suffering from genitourinary disease. LUGPA currently represents 145 urology group practices in the United States, with more than 2200 physicians who, in 2016, collectively provided approximately 35% of the nation's urology services. From the outset, LUGPA's mission has been to advance the independent practice of urology by advocating for independent physicians' ability to access technology in their practices; to cultivate clinical, business, and administrative excellence; and to recruit and support future leaders in urology. LUGPA is an organization of practices, not a medical society—as such, it occupies a unique niche in the specialty of urology.

At present, LUGPA's sole mission is to preserve and advance the independent practice of integrated urology. As current and former LUGPA leaders, each of us has dedicated our time and efforts to support this mission, building on the efforts of our predecessors. To enhance that mission going forward, we offer this article summarizing the history, activities, and accomplishments of LUGPA and acknowledging current-day competitors to our mission; we encourage all LUGPA members to openly discuss how we can consistently prioritize our patients and our profession.

History

As recently as the late 1990s, many US metropolitan areas began to see small urology practices coalesce into larger regional integrated practices. This early consolidation was spurred by a desire to achieve scale in order to access professional management, develop clinical protocols and centers of excellence, obtain capital (to allow for the growth of facility services, such as ambulatory surgery, imaging, and radiation centers), strengthen negotiating power with third-party payers, and better navigate burgeoning administrative and regulatory burdens. Around this time, a handful of early consolidated groups began meeting informally each year to compare notes and to discuss clinical and business best practices.

In 2008, the physician leaders of large urology group practices began to recognize the need for a formal association to help meet the challenges of the future. To that end, two nascent organizations developed: US Urology, which focused on data aggregation and treatment pathways, and a clinical roundtable gathering sponsored by TAP Pharmaceuticals. To their credit, the physicians involved in these efforts quickly realized that it was not in the best interest of independent, integrated urology groups to splinter what were, at that time, a relatively small number of potential member practices. These physicians had the vision to unify their collective objective by consolidating the boards and bylaws of the two entities into a single group. Thus, LUGPA's inception resulted from compromise and a willingness to prioritize the needs of the specialty above the interests of individual physicians leading the two nascent organizations.

LUGPA's success in defending the right of patients to access integrated, independent care at the site of their choosing has led many to believe that political advocacy was the initial goal of the organization; in fact, nothing could be further from the truth. LUGPA was initially established to enhance communication between large urology groups, allow for benchmarking of operations, and promote quality clinical outcomes.

Shortly after LUGPA's inception, however, events occurred that dramatically altered its course as an organization. Efforts gained momentum in Congress and several statehouses to prevent integrated urology practices from offering services such as diagnostic imaging, clinical and anatomic pathology, and radiation oncology. These efforts were led by interests in the healthcare community with historical monopolies on these ser-

a single voice. In 2011, LUGPA subsumed AICC's resources and mission. From that point forward, the foundation of LUGPA's efforts has been to objectively analyze data and present the results to legislators and regulatory bodies in the form of detailed public commentary. These efforts are enhanced by targeted political advocacy that enables key decision makers to understand the vital role that independent urology practices play as a competitive counterbalance to less convenient, more expensive monopolistic sites of urology service.

Focusing on what is in the best interest of the patient and demonstrating that independent, integrated urologic care aligns with the nation's healthcare objectives has enabled LUGPA to be the principal organization bolstering the sustainability of independent urology and protected access to care for millions of US patients.

vices, which are crucial for urology practices to develop urocentric centers of excellence, improve patient access to care, and reduce healthcare costs. As a new organization, LUGPA had neither the infrastructure nor the resources to engage in this struggle. Therefore, in 2009, a group of Northeastern physician executives created a parallel organization for the sole purpose of political advocacy. This entity, Access to Integrated Cancer Care (AICC), was able to effectively fundraise, which enabled detailed actuarial analysis of clinical utilization patterns. For the first time, independent, objective analysis² debunked the narrative of historical monopoly specialists, who were promoting the false notion that utilization patterns in integrated urology were financially motivated.

During this period, there was considerable overlap in the leadership and membership of LUGPA and AICC. Just as at LUGPA's inception, physician leaders recognized that the independent practice of urology was best served by

Current Health Policy and Advocacy Objectives

Although the existential threat to independent urology during the early part of this decade has been mitigated, new challenges have arisen. Independent urology practice is now confronted by numerous practice-changing competitive stakeholders, including hospital acquisitions, management services organization models, and other evolving for-profit entities. With crucial support from its member groups, LUGPA continues to successfully oppose those who wish to limit independent urology practice. Current areas of focus include:

- Continued vigilance in maintaining patients' access to technology by preserving the inoffice ancillary services exception to Stark law (IOASE);
- Leveling the reimbursement playing field so that hospitals and hospital-employed physicians and independent urologists receive comparable (site-neutral) payments;

- Encouraging the development and availability of urology valuebased care models that resulted from eliminating the Medicare Sustainable Growth Rate (SGR) formula and passage of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA);
- Reforming the Stark and anti-kickback statutes so that independent physicians can participate in alternative payment constructs, like those that Accountable Care Organizations (ACOs) afford health systems and their employed physicians;
- Maintaining the public's access to prostate-specific antigen (PSA) testing by opposing downgrading of the PSA test by the United States Preventive Services Task Force (USPSTF) and promoting legislation to reform the USPSTF; and
- Consistently working to protect reimbursement for key urology services by providing regular written comments and personally interacting with decisionmakers at Centers for Medicare & Medicaid Services (CMS) and in Congress.

In order to achieve these goals, LUGPA has created a dedicated and dynamic health policy and advocacy apparatus. Key elements of this capability include dedicated and knowledgeable physician volunteers, professional policy advocates on continuous retainer from both sides of the aisle, public relations consultants who also are on continuous retainer, and frequent collaboration with healthcare attorneys who assist LUGPA in preparing written responses to regulatory initiatives. However, as important as these elements are, the core of this strategy is promoting direct engagement between LUGPA member practices and legislators

on committees of jurisdiction in both the United States House of Representatives and Senate. This engagement has been hugely successful: cross-referencing the Medicare provider database with Federal Trade Commission (FTC) donation records for the current political cycle indicates that urologists in LUGPA groups are 295% more likely to contribute than non-LUGPA urologists.3 In addition, although LUGPA members numerically constitute fewer than one-fourth of the nation's urologists, they account for an astonishing 62% of current federal political contributions by urologists.

Although a complete discussion of LUGPA's policy and advocacy activities and achievements exceeds the scope of this article, we wish to highlight a few examples and share details regarding the priorities summarized above.

Site-neutral Payments

A key legislative and regulatory priority has been to level the playing field between independent physicians and hospital systems regarding access to care and equivalent compensation. In recent years, hospital acquisitions of physician practices have undermined independent physician practices' viability, reduced options for care, and fueled healthcare costs without discernably improving quality of care.4-6 Perhaps more troubling is that these acquisitions have led to hospital system consolidation in many markets7; costs further escalate when physician practices are acquired by these monolithic health care entities.4

LUGPA's efforts to combat this trend led to the first-ever inclusion of "site of service" language in the Bipartisan Budget Act of 2015, which ended preferential reimbursement for newly acquired physician practices that do not operate

near a hospital main campus. In late 2018, CMS promulgated additional related regulation that LUGPA has supported and commented upon but that is being challenged by the hospital lobby. If these regulations are fully implemented, it will further curtail the disparity in reimbursement between hospitalemployed physicians and independent physicians. These efforts include advocating for reform of the fatally flawed 340B drug acquisition program, which has been demonstrated to have been the source of major system abuse and a vehicle used by hospitals to further monopolize loco-regional health care services.8,9

Value-based Care Models

LUGPA and other groups successfully advocated for the passage of MACRA, which repealed the outdated SGR reimbursement model and established alternative payment models (APMs) that incenhigh-value, cost-efficient care. In fact, LUGPA was a pioneer in development of value-based care models in urology, being the first entity to submit a urologyspecific APM to CMS.10 However, this model and others could not be implemented because independent practices cannot perform realworld testing of these structures; furthermore, waivers that were granted to hospitals to develop crucial physician relationships to share economic risk were not extended to independent physicians—such relationships are specifically prohibited by law. Expansion of the availability of value-based care models in the independent practice setting is vitally important to the nation's healthcare fiscal security data clearly illustrate that, just as in fee-for-service models, independent physician practices are highquality, cost-effective alternatives to facility-based care.11

To remove impediments to the development of value-based care models, during both the prior and the current session of Congress, LUGPA helped successfully promote the introduction of bipartisan, bicameral legislation that will reform these outdated restrictions and afford independent physicians the same waivers as granted to hospitals; LUGPA is currently leading the charge in advocating for the bill's passage.¹²

Through formal comment letters and face-to-face meetings with CMS, LUGPA has time and again successfully reversed proposed cuts in reimbursements for critical urologic services. In 2015, LUGPA went beyond its interactions with CMS and initiated a robust grassroots effort that led to congressional action, averting CMS's proposed draconian cuts to radiation reimbursement in free-standing radiation facilities.

Ancillary Services

Defending the rights of patients to seek integrated urologic care at the site of service of their choosing has been a foundational issue for LUGPA for nearly a decade. Central to this is the preservation of the IOASE, whose elimination would severely limit patient access to services offered through integrated care models. To date, LUGPA has successfully engaged policy makers on this issue and has demonstrated that access to technology by independent practices both reduces US healthcare costs and improves patient access to care. Detailed descriptions of these efforts have been published and will not be reiterated here, but these analyses have thwarted the efforts of historical monopoly specialists who have been continuously lobbying for repeal of the IOASE. These efforts now garner decreased attention; however, education and advocacy

have remained important to update legislators when IOASE repeal interests intermittently engage.¹³

Reform of the USPSTF

Finally, LUGPA continues to advocate for greater transparency and accountability from the USPSTF in the wake of its 2012 blanket recommendation against PSA screening. 14 Many clinicians have witnessed the effects of this recommendation—an unfortunate increase in the number of patients presenting with newly diagnosed, metastatic prostate cancer. 15 After extensive input from LUGPA and other organizations, the USPSTF in May 2018 altered its PSA screening recommendation. 16

Although the PSA testing controversy thrust the USPSTF into the limelight for urologists, this was not the first controversial recommendation by the task force. In 2009, the USPSTF recommendation on routine mammography prompted such outrage that the United States Congress amended the Patient Protection and Affordable Care Act (PPACA) to prevent implementation of this recommendation.¹⁷ The task force also inexplicably maintains that testicular selfexamination is harmful to patients and should be discouraged.18 These outlandish recommendations can continue because the USPSTF processes are essentially exempt from public scrutiny and are not subject to oversight. Most governmental advisory committees such as the USPSTF are subject to The Federal Advisory Committee Act (FACA).19 This is important because FACA establishes several critical transparency and procedural requirements that ensure stakeholders and the general public understand how decisions are being made and can engage meaningfully in those deliberations and in policy development. Yet these

reasonable requirements do not apply to the USPSTF: the USPSTF charter specifically exempts the USPSTF from FACA.²⁰

LUGPA was among the first organizations to recognize that reform of the USPSTF was needed, and that these reforms went beyond the needs of the specialty of urology. LUGPA also was one of the initial proponents of the USPSTF Transparency and Accountability Act, which would require the USPSTF to publish its plans for reviewing preventive services, to share reports and recommendations for public comment, and to convene stakeholders to provide feedback and guidance. 22

Integrative Care and Healthcare Management

Notwithstanding recent federal efforts to reform the healthcare system, the cost of healthcare in the United States continues to rise. In particular, the many advances in cancer care have been attended by significant cost escalations and an increase in administrative and regulatory responsibilities. These factors have amplified urologists' workloads and overhead, which presents a challenge for dedicated and committed urologic care teams seeking to provide excellent care while remaining economically viable. Burnout in urology is increasing, even as an aging population (currently, approximately 10,000 individuals age into Medicare daily) increases demand for urologic services.23-25 Innovation and collaboration will be required for independent urology to endure and thrive.

In response to these challenges, LUGPA has worked closely with its member groups to facilitate collaboration amongst urologists, medical and radiation oncologists, and primary care providers in both private and academic settings. LUGPA's 19-chapter guidebook, *Practice Management for Urology Groups*, shares essential insights on topics such as the legal and economic implications of group practice; operational and governance structures; insurance and billing issues; medical imaging; integrating service lines to expand access to care; telemedicine; creating a urology-specific laboratory; and establishing centers for ambulatory surgery, radiation oncology, advanced prostate cancer care, and women's pelvic health services.^{26,27}

LUGPA is working closely with its members as they strive to meet the challenges of transitioning to value-based care. To help urologists succeed under MACRA, LUGPA has submitted to the federal government urology's only alternative payment model, which is designed to promote active surveillance for prostate cancer. In addition, LUGPA has sponsored several other pathway-based algorithms projects, including for minimizing prostate biopsyassociated sepsis and pathways for the management of advanced prostate cancer, bladder cancer, and voiding dysfunction. LUGPA's leading role in transforming urologic care in the independent practice community has been widely recognized, and the resulting benefits to the public are amongst LUGPA's proudest achievements.

A practice's ability to compare its financial and clinical performance with that of other urology groups is essential for success and quality improvement. LUGPA annually deploys detailed, relevant, urology-specific surveys to collect regional and national data against which member groups can benchmark themselves. In addition to benchmarking, strategic planning can help urology practices continue to thrive and grow in the ever-changing healthcare environment. The

investment of time and resources is only worthwhile, however, if the resulting strategic plan is clear, organized, detailed, and appropriately adapted to a practice's culture and needs.²⁸ Using practical tips and real-world examples, LUGPA's Strategic Plan Toolkit shows members how to identify core strategies and to develop corresponding mission and vision statements, strategic priorities, action items, and metrics for success.²⁹

Finally, in 2017, the LUGPA FORWARD program was initiated to cultivate and encourage the next generation of urology leadership. LUGPA FORWARD identifies and engages LUGPA members who have been in practice for less than 15 years to help this dedicated segment of LUGPA members collaborate and network, find mentors, and surmount shared challenges during the experience and evolution of early-career practice. LUGPA FORWARD also addresses challenging aspects of early-career practice that previously tended to go undiscussed, such as pay disparities, leadership skills, and work-life balance.

Given its ongoing and future benefit to the independent practice of urology and the US healthcare system, the importance of LUGPA's sustainability, non-profit status, and primary mission cannot be underappreciated. LUGPA has and will continue to lead efforts to protect and advance integrated practice and to promote systems for healthcare management that best meet the needs of both patients and clinicians.

Medical Education

Recent advances in diagnostic and surgical technologies, as well as numerous approvals of new systemic therapies, have heightened the need for accurate, relevant, fair-balanced, not-for-profit urologic education. LUGPA is deeply committed to this goal and has continually innovated new educational models to provide accessible, rigorous educational offerings to our member urologists and to clinicians in residency and fellowship programs.

Each year, at the annual LUGPA meeting, more than 500 individuals from more than 145 practices throughout the United States gather to learn from experts about topics such as best practices for prostatic biopsy, optimizing transurethral resection of a bladder tumor (TURBT), incorporating immuno-oncology into an independent urology practice, screening for hereditary prostate cancer, practice buy-ins and buy-outs, and pragmatic solutions for telehealth.30 LUGPA also organizes five to six annual regional meetings for urologists, nurse navigators, research coordinators, and others who cannot attend the annual LUGPA meeting or who would like to engage and learn more about both general and region-specific topics.

LUGPA also understands the need to educate residents, so, in 2019, it inaugurated its first-ever Rising Chief Residents Summit in San Diego. This fair-balanced educational forum addressed career options in academic, private practice, and employed urology; the state of the US urology workforce; contract negotiations; and political advocacy. Residents who attended reported that they were extremely satisfied with the curriculum and that these topics were not addressed in their residency programs. LUGPA plans to expand the program in future years.

In 2013, LUGPA partnered with MedReviews, LLC, to make *Reviews in Urology* its official peer-reviewed journal. The journal covers the

latest diagnostic and therapeutic advances in a wide range of urologic conditions.

In 2015, LUGPA initiated its regional Integrated Urology Practice Forums, which are held several times per year throughout the United States to discuss pragmatic solutions to challenges such as MACRA implementation, data security, and the development of subspecialty service lines.

LUGPA further expanded its offerings by again partnering with MedReviews to launch Prostate Cancer Academy (2016) Bladder Cancer Academy (2017), which annually convene urology residents, fellows, LUGPA members, and others to discuss the latest advances in prostate and bladder cancer diagnosis, medical and surgical management, and surveillance and care.31,32 These academies are an invaluable opportunity to learn and ask questions of thought leaders during this time of rapid diagnostic and therapeutic development. Presentations are recorded and are available online (http://medreviews .com/conferences). After attending these meetings, most LUGPA groups have been able to implement similar clinics, thereby directly enhancing the communities they serve. Each of these educational programs has been developed without any financial incentivization for the organization or its member practices.

Also, in 2017, the LUGPA Virtual Crossfire series began offering webbased presentations of clinical and business education sessions to members who interact with expert faculty by means of audience polls and real-time question-and-answer sessions.³³ Sample topics have included the creation of advanced bladder cancer clinics, current and future therapiesfornon-metastaticcastration-resistant prostate cancer, challenges

faced by early-career urologists, and creating and sustaining successful partnerships and collaborations.

Finally, in 2018, LUGPA launched LUGPA Onsite, in which educational programs are held at LUGPA member sites to cover practice-oriented topics, such as how to optimally integrate advances in diagnostics, imaging, and therapeutics, establish bladder, kidney, and advanced prostate cancer clinics, and the integration of administrative, physician, and advanced practice provider roles.³³

When Boundaries Blur

A strength of LUGPA has been the active engagement of entrepreneurial physician leaders who have generously given of their time and efforts to defend the independent, integrated model of urologic care. As LUPGA's influence has expanded, this direct engagement has led to challenges, particularly with respect to potential conflicts of interest.

Conflicts of interest have existed for as long as corporate interests have been active in medical care. Physicians may have financial relationships with industrysponsored programs, whether through research funding, advisory boards, consulting, speaker bureaus, or personal investments. The problem arises when these relationships are not disclosed, or when physician leaders fail to appropriately recuse themselves from non-profit roles or activities that overlap with their for-profit endeavors. The goals and actions of a competitive for-profit entity could inadvertently harm the mission, goals, and activities of the non-profit organizations we serve.

Recent failures by prominent physicians to disclose and manage conflicts of interest at the University of Texas MD Anderson Cancer Center and Memorial Sloan Kettering Cancer Center illustrate the extent of this problem and the extraordinary degree to which medicine and industry are entangled.³⁴⁻³⁶ Unfortunately, these were not isolated incidents—in a recent study of 344 oncologist authors, 32% did not fully disclose payments from clinical trial sponsors.³⁷

Like MD Anderson and Memorial Sloan Kettering, LUGPA is a nonprofit organization that must annually disclose its organizational structure, revenue streams, expenditures, program service activities, and potential conflicts of interest, including familial and business relationships amongst organizational leaders and with taxable (forprofit) entities. This practice helps ensure that LUGPA and all other non-profit organizations earn their tax-exempt status and stay focused on their mission, and not on individual or practice-level investments.

LUGPA board members are required to disclose conflicts of interest at every meeting and recuse themselves from decisions and discussions when appropriate. Disclosures are distributed in writing at board meetings, and potential conflicts of interest are discussed openly. This practice is not only expected but encouraged and welcomed, in keeping with LUGPA's culture of transparency, trust, and mutual support.

With so many different stake-holders in healthcare today, boundaries and conflicts of interest are becoming ever more complex, and our full disclosures are vitally important. As independent practitioners, many of us enjoy contributing to a diverse range of non-profit and for-profit organizations. Each of us has needed to ask ourselves, at one time or another, whether a financial relationship is unduly affecting our judgement and whether we should therefore recuse ourselves from certain activities.

It is thus vitally important that LUGPA members, now and in the future, recognize and communicate conflicts of interest, fully disclose them, and openly discuss these concerns without fear of personal reprisal from for-profit entities.

It is only in this fashion that LUGPA can continue to be an effective advocate for our patients and our member practices.

Summary

Eleven years after LUGPA's inception, its passion and commitment to protecting and preserving the independent practice of urology remain stronger than ever. Without LUGPA, there would be far fewer opportunities for independent urology practices, fairbalanced education, networking, or external benchmarking than we have today. LUGPA groups have been able to integrate essential urologic services at a lower cost than their hospital competitors. Many of our member practices have become urologic centers of excellence with subspecialty lines of service and innovative, costeffective pathways that optimize patient outcomes.

Innovation springs from independence, not bureaucracy. independence practitioners have the freedom and flexibility to share decision-making with their patients and to rapidly implement, test, and adapt new diagnostics, therapeutics, and pathways. Backed by a robust organization such as LUGPA, independent urologists can implement innovative approaches that significantly improve the health of their patients and the sustainability of their practices. Such nimbleness is especially crucial given the current

rapid pace of change in urology. Aligning the interests of patients, providers, and payers by promoting value-based care at independent, integrated physician practices is LUGPA's ongoing mission; our rallying cry should be to continue that mission in an open, transparent, and inclusive fashion.

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